UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
PO Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,738	05/09/2001	Thomas R. Coolidge	P03660US5	4849

27141 7590 08/22/2003

MCKEE, VOORHEES & SEASE, P.L.C.
ATTN: BIONEBRASKA
801 GRAND AVENUE, SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,738	COOLIDGE ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Paper No. 7* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' preliminary amendment filed 7 May 2001 (Paper No. 7) as to cancellation of claims 1-13 has been entered. Thus, the pending claims 14-23 are under examination to the extent that they are drawn to the elected invention.

Specification/claim Objections

The disclosure is objected to because of the following informalities:

In page 1, line 10, "GLP-1" should be fully spelled out for the first instance of use. See also page 3, line 1 from the bottom "MI"; page 4, line 2 from the bottom "DIGAMI"; page 8, line 12 "NADH" and page 9, line 24, "GIK".

In page 13, line 25, "SEQ. ID NO:1" should be changed to "SEQ ID NO:1". The same changes should be made throughout the specification.

In claim 17, "the" should be deleted before "administering".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a method of metabolic intervention using GLP-1 to improve ischemic condition. Applicant is not in possession of a method stated above involving use of GLP-1 analog.

There is insufficient description or/and guidance as to how to make and use of the said GLP-1 analog. Further, the specification fails to describe additional representative species of the analogs thereof. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 112, the second paragraph

Claims 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites "improve the function of ischemic and reperfused tissue"; the recitation is unclear as to what is the said function to be improved, and what is the improvement. Also, claim 14 is indefinite in the recitation "GLP-1" which should be spelled out for the first time recited in the claims, or the recitation renders the claim unclear since "GLP-" can refer to the tripeptide. "The dependent claims are also rejected.

Claim 15 sets forth 'analog thereof" which renders the limitation of claim 15 broader than that of claim 14 from which claim 15 depends. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 15 recites the broad recitation of GLP-1 "analog" which encompasses molecules structurally and/or functionally homologous to unmodified GLP-1 polypeptide, and the claim a5 also recites "GLP-1" *per se*, which is the narrower statement of the range/limitation.

Claim 20 recites "continues thereof"; the recitation is unclear as to whether or not every 4 hours the administration is carried out, and what is the end point for the continued administration.

Claim 21 recites the limitation "the need for amelioration of tissue damage...". There is insufficient antecedent basis for this limitation in claim 14 form which claim 21 depends.

Claim 22 recites the limitation "the medical procedure". There is insufficient antecedent basis for this limitation in claim 14 from which claim 22 depends.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Galloway, J. A. et al. (US Pat. No.6410513).

Galloway et al. teach the pharmaceutical composition comprising GLP-1 (glucagon-like peptide 1) and a pharmaceutical acceptable carrier (see the patent claims 1 and 5), as applied to claim 23 of the current application.

Note that the recited use in metabolic intervention refers to an intended use for the claimed composition and there is no patentable weight associated with the use of the composition which structure and biological activity will not be altered due to the use of the composition to treating a disease state or improve the function of ischemic.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 14-20 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 1-8 and 10 of US Pat. No.6429197. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 1 of 6429197 sets forth a method of improving the function of the ischemic and reperfused brain comprising administering a composition comprising GLP-1 and a pharmaceutical carrier to a subject (see the patent claim 1, title of invention, and column 2, lines 33-35). Thus, the claim 1 of 6429197 discloses the common subject matter of claims 14-15 of the current application.

Claims 2, 3 and 4 of 6429197 are identical to claims 16, 19 and 17 of the current application, respectively.

Claim 3 of 6429197 discloses the same subject matter as claims 18 of the instant application regarding the method comprising concurrent administration of glucose.

Claim 8 of 6429197 is an obvious variation of claim 20 of the instant application since the invention of 6429197 is directed to the preferred method of administration of the GLP-1 peptide which is performed through a continuous application of the peptide (see column 8, lines 1-8).

Claims 5-7 and 10 of 6429197 set forth the limitations of the dosage and route for administering GLP-1 to the subject, which encompass the limitations of the instant claims 14 and 17-20 with respect to the GLP-1 administration thereof. Therefore, the claims stated above

in the instant application and those in US Pat. No. 6429197 are obvious variation, and they are not patentably distinct from each other.

Claims 14-20 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 1-5 and 8-13 of US Pat. No.6284725. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-2 of 6284725 disclose a method of ameliorating organ tissue injury (i.e., improve the function of ischemic and reperfused tissue which is the subject matter of the patent invention, see title and column 1, lines 12-14) comprising administering a composition comprising GLP-1 and a pharmaceutical carrier to a subject (see the patent claim 1). Thus, the claim 1 of 6284725 discloses the common subject matter of claims 14-15 of the current application.

Claims 3, 4, 5, 8 and 9 of 6284725 are identical to claims 16, 17, 18, 19 and 20 of the current application, respectively.

Claims 4 and 10-13 of 6284725 set forth the limitations regarding the dosage and route for administering GLP-1 to the subject, which are applicable to the limitations of the instant claims 14 and 17-20 with respect to the GLP-1 administration thereof.

Therefore, the claims stated above in the instant application and those in US Pat. No. 6284725 are obvious variation, and they are not patentably distinct from each other.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this

application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. The terminal disclaimers signed by the assignee must fully comply with 37 CFR 3.73(b) with respect to the above rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel W. Liu, Ph.D.

August 15, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER